Remarks

Favorable consideration of this application is respectfully requested in view of the foregoing amendment and the following remarks.

Claims 1-19 are pending. Claims 1, 12, 13, 18 and 19 have been amended and claims 2-5 and 14-17 have been cancelled without prejudice. Support for the recitation of the compound, 1-(4-chloroanilino)-4-(4-pyridylmethyl)phthalazine, in claims 12, 13 and 19 can be found in the specification, e.g., pages 11 and 13. New claim 20 has been added. Support for the compound, 1-(4-chloroanilino)-4-(4-pyridylmethyl)phthalazine, recited in claim 20 is found in the specification, e.g., pages 11 and 13. No new matter has been added.

Accompanying this amendment is an information disclosure statement listing the reference, US2003/0171375A1 (the '375 reference), which is the published application of U.S. application no. 10/364,606. In particular, the Examiner's attention is directed to the '375 reference on page 1, paragraphs 1-14; page 7, paragraph 127; and page 8, paragraph 133.

Claims 1-19 have been rejected under 35 U.S.C. §112, first paragraph. The Examiner contends that the specification, while being enabling for certain retinal diseases, does not reasonably provide enablement for all retinal diseases. Before addressing the rejection, it is noted that claims 1 and 18 has been amended to state the particular retinal diseases set forth in original claims 2-5 and 14-17. Accordingly, claims 2-5 and 14-17 have been cancelled without prejudice and the §112, first paragraph rejection is responded to with respect to amended independent claims 1 and 18.

Applicants respectfully disagree with the Examiner's conclusion and submit that amended independent claims 1 and 18 are enabled by the specification for the following reasons.

The Examiner cites the Wands factors in determining whether the disclosure meets the enablement requirements. In particular, the Examiner indicates that with respect to "the state of the prior art Wands' factor" that

> "the prior art does not recognize all neovascular diseases can be treated with one group of compounds and that according to LANGE, current Medical Diagnosis & Treatment, the treatment for macular degeneration and diabetic retinopathy is different."

The Examiner also states in part with respect to "the amount of direction or guidance presented" Wands' factor that

> "Applicants' specification does not set forth a representative [number of] phthalazine compounds capable of treating a representative number of retinal disorders."

The Examiner further states with respect to the "quantity of experimentation necessary" that

> "since compound structure and activity for each pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all phthalazine compounds which are capable of treating all retinal disorders."

With respect to enablement, it is noted that a specification is presumed to be in compliance with the enablement requirement, unless there is reason to doubt the objective truth of the statements contained therein. As stated by the Federal Circuit, in *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (CCPA 1971)

> "it is incumbent upon the Patent Office, whenever a rejection on this basis [112, first paragraph] is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence [emphasis added] or reasoning which is inconsistent with the contested statement."

In the present case, the specification on page 15 includes an example of topical administration of the phthazine compound PTK787. In addition, the specification on page 11 specifically recites a representative number of phthalazine compounds that are capable of being topically administered to the retina.

The Examiner, in merely providing blanket assertions that 1) the state of the art does not show that retinal diseases can be treated with one compound and 2) one of ordinary skill in the art would be burdened with undue experimentation, has failed to provide objective evidence, i.e., prior art references, etc., which cast doubt that the specifically recited compound of formula I, e.g., the specific compounds described on page 11 of the specification, would not be effective in treating the retinal diseases as set forth in amended independent claims 1 and 18. Accordingly, the Examiner has not met her initial burden of providing objective evidence to back up her assertion of lack of enablement as is required by law.

In view of the above, withdrawal of the rejection of Claims 1-19 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 1-17 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,271,233 (the '233 patent). In response to this rejection, a terminal disclaimer is submitted herewith, disclaiming the term of any patent that issues from the present application that would extend beyond the expiry of the '233 patent.

In view of the above, withdrawal of the rejection of claims 1-17 under the doctrine of obviousness-type double patenting is respectfully requested.

Claims 18-19 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO98/35958 (WO'958). In particular, the Examiner states that

> "the WO Patent teaches the use of the claimed compounds in a pharmaceutical formulation with angiogenesis inhibitory activity. See the abstract. To use an old composition in a squeezable container does not create a patentably distinct composition."

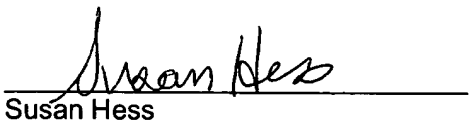
Applicants respectfully disagree with the Examiner's conclusion and submit that WO'958 does not anticipate the presently claimed invention as defined in amended independent claim 18.

While WO'958 indicates that the phthalazine compounds have angiogenesis inhibiting activity and that a number of diseases are known to be associated with deregulated angiogenesis, for example retinopathies, psoriasis, haemoangioblastoma, haemagioma and neoplastic diseases (solid tumors), WO'958 does not describe the specific retinal diseases recited in amended independent claim 18 nor give any hint that the compound of formula I can be effective in treating the specific retinal diseases recited in amended claim 18. Since WO'958 does not specifically describe the retinal diseases set forth in amended independent claim 18, WO'958 does not anticipate claim 18.

In view of the above, withdrawal of the rejection of claims 18-19 under 35 U.S.C. §102(b) is respectfully requested.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, she is requested to call the undersigned at the number listed below.

Respectfully submitted,



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